rejection as being indefinite related to the deletion of the word "type" and deletion of the phrase "wherein said".

No new matter within the meaning of § 132 has been introduced by any of the claim amendments.

Accordingly, Applicants respectfully request the Examiner to enter the amendments and to reconsider and allow all claims pending in this application.

## 1. Rejection of Claims 5-6, 8 and 10-19 under 35 U.S.C. § 112, ¶ 2

The Office Action rejects claims 5-6, 8 and 10-19 under 35 U.S.C. § 112, ¶ 2 as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Office Action states:

> Claims 5, 6 and 8 recite the limitation "said self hardening type chemicals" in line 2. There is insufficient antecedent basis for this limitation in the claims, as claims 1 and 3 do not recite the word "type". Also, the use of the word "type" makes the scope of claims 5, 6 and 8 unclear, for reasons stated in prior Office Actions. Claim 10 contains "wherein said" as the last two words, due to an apparent typographical error. It is not clear whether any further limitations were intended to be added to the

> claim. Also, with respect to claims 11, 18 and 19, it is not clear what is meant by a "water cellulose type resin", for substantially similar reasons to those provided above pertaining to use of the word "type".

Applicants respectfully traverse the rejection. However, Applicants have amended claim 5 to delete the term "type" and canceled claims 6 and 8.

Applicants have further amended claim 10 to delete the phrase "wherein said" in the last line of the claim.

Still further, Applicants have canceled claims 11 and 18-19. Notably, the incorporation of claim language from claims 18 and 19 into claims 1 and 3, respectively recite, "a water soluble cellulose resin" wherein the term "type" is no longer recited.

Accordingly, Applicants respectfully submit that the presently pending claims particularly point out and distinctly claim the subject matter of the invention and request the Examiner to reconsider and withdraw the rejection.

2. **Rejection of Claims 1, 3, 5-6, 8, 10 and 12-17 under 35 U.S.C. § 103(a)**

The Office Action rejects claims 1, 3, 5-6, 8, 10 and 12-17 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,919,151 ("Grubbs et al.") in view of "Creating Cataract in a Pig Eye", J. Refractive Surg., May 1999 ("Sugiura et al."), and further in view of "Polymer Gelation Due to the Self Assembly of Dibenzylidene Sorbitol and Its Derivatives", Statistical Thermodynamics N.C. State Univ., (June 01,1999) ("Wilder"). The Office Action states:

> Grubbs discloses in Figures 1-5 and in column 2, lines 17-66 of the specification a method and device comprising an eye which is prepared by creating an empty lens by aspiration, injecting a polymer into the empty and curing the polymer to lens to create an artificial lens. While Grubbs fails to disclose the use of a pig eye to simulate cataract, the use of hardening chemicals to create a cataract in a pig eye for simulated surgery is known. Sugiura discloses a model of an eye with cataract comprising a pig's eye which has hardening chemicals injected into the lens to form the model. It would have been obvious to one of ordinary skill in the relevant art to modify the model disclosed by Grubbs by injecting chemicals into a pig eye for the purpose of creating a false cataract for use in simulated surgery. Grubbs as viewed with Sugiura fails to the injection of a self-hardening chemical selected from the group

> listed in claim 1 into the lens. Such self-hardening chemicals are known. Wilder discloses that dibenzylidene sorbitol is a self-hardening chemical which forms three dimensional fibrillar networks without the need to interact chemically with other substances. It would have been obvious to one of ordinary skill in the relevant art to modify the model disclosed by Grubbs as viewed with Sugiura by injecting dibenzylidene sorbitol into an empty lens for the purpose of hardening the eye to produce a simulated cataract without requiring the curing process as described by Grubbs. Also, although the location of the injection of claim 5 is not explicitly disclosed by Grubbs or Sugiura, the claimed location does not appear to yield any unexpected advantages over the location disclosed by Sugiura, and thus would also have been obvious to one of ordinary skill in the art as an aesthetic choice of design. With respect to claims 12, 14 and 16, while Grubbs does not specifically use the word "phacoemulsification" in its description, Grubbs does disclose the use of high frequency vibrations to cause ultrasonic disintegration of the lens prior to its removal from the lens, thus at least suggesting if not discloses the use of phacoemulsification in emptying the lens capsule of the eye.

Applicants respectfully traverse this rejection because a *prima facie* case of obviousness has not been established. One of ordinary skill in the art would not have had any motivation to combine the cited references to arrive at the presently claimed invention. Although it is suggested that one of

ordinary skill would have been motivated to combine the dibenzylidene sorbital ("DBS") of Wilder et al. with a crystalline lens to form a cataract surgery model, there is a complete lack of any such suggestion in the prior art or within the knowledge of one of ordinary skill in the art at the time of invention. Wilder et al. is a very general teaching regarding the molecular configuration of DBS in its native state and gel form. Nothing in Wilder et al. or the cited references would have suggested the addition of the relatively new compound of DBS at the time of invention into a model for cataract surgery.

Turning to the rule, the Federal Circuit held that a *prima facie* case of obviousness must establish:

(1) some suggestion or motivation to modify the references;

(2) a reasonable expectation of success; and

(3) that the prior art references teach or suggest all the claimed limitations. Amgen, Inc. v. Chugai Pharm. Co., 18 USPQ2d 1016, 1023 (Fed. Cir. 1991); In re Fine, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988); In re Wilson, 165 USPQ 494, 496 (C.C.P.A. 1970).

Regarding the *prima facie* element of suggestion or motivation to modify the references, the Federal Circuit has

clearly stated that only three possible sources for a motivation to combine references exist: the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art. In re Rouffet, 47 USPQ2d 1453, 1457-58 (Fed. Cir. 1998). Without a motivation to combine, a rejection based on a *prima facie* case of obvious is improper. Id.

Moreover, the level of skill in the art cannot be relied upon to provide the suggestion to combine references. Al-Site Corp. v. VSI Int'l Inc., 50 USPQ2d 1161 (Fed. Cir. 1999). It is imperative to ascertain that the cited references provide a sufficient basis for one of ordinary skill in the relevant art having the reference before him to make the proposed substitution, combination, or other modification. In re Linter, 173 USPQ 560, 562 (C.C.P.A. 1972).

In other words, there must be some teaching, suggestion, or motivation to make the claimed limitations found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. Id. The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and

the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art. In re Kotzab, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000).

In the present application, one of ordinary skill in the art at the time the invention was made would not have had any motivation to combine the DBS of Wilder et al. with the surgery models of Grubbs et al. and Sugiura et al. There is no teaching in any of the references that either explicitly or implicitly teaches the combination of DBS in any of the references.

Turning first to Grubbs et al., the scope of the reference can be summarized as a method for preparing a transparent polymer lens by irradiating the lens with an ultrasonic wave to liquefy the contents, removing it by aspiration so as to prepare an empty capsule, inserting a prepolymer (lower polymerized polymer whose degree of polymerization is smaller than 10, which is called an oligomer in the UV hardening resin field), removing oxygen, and polymerizing by exposure to visible-to-near-UV radiation. In other words, Grubbs et al. teaches the use of light energy to harden a resin and a photosensitive polymerization initiator or a prepolymer having a functional

substance. Grubbs et al. fails to teach or even suggest the use of a self-hardening type polymer of the claimed invention.

Although it is alleged that the use of hardening chemicals for preparing a pig's eye with cataract for a simulating operation is taught by Sugiura et al., the teaching of Sugiura et al. solely relates to denaturing and hardening the protein **inside** the pig's eye by inserting formalin and alcohol into the crystalline lens capsule. As noted previously, when formalin and alcohol are inserted into the empty crystalline lens capsule, the lens does not harden as is presently claimed.

Instead, Sugiura et al. teaches that the protein or peptide which originally exists in the pig's eye is modified by injecting high concentrated formalin or alcohol thereby causing sedimentation and viscosity increase. In other words, Sugiura et al. teaches an *in vivo* solution in crystalline lens capsule solidified by mixing with chemicals, which is completely different from the presently claimed self-hardening polymer. Clearly, one of ordinary skill would not have had any indication as to the desirability of using the DBS of Wilder et al. in the surgery models of Grubbs et al. and Sugiura et al.

Grubbs et al. and Sugiura et al. also retain several disadvantages insofar as formalin is toxic and becomes muddy after insertion into a crystalline lens. In particular, the loss in transparency from formalin becoming muddy significantly reduces the usefulness of the lens as a cataract surgery training model.

Turning to the Wilder et al. reference, it is noted that although the Office Action states that one of ordinary skill would have been motivated to use DBS, Applicants note that Wilder et al. is only a very general teaching of DBS. Wilder et al. only teaches that DBS is a low molecular organic compound which can self-organize as three dimensional fibrillar networks in polymer and the particular basic interaction DBS has with surrounding molecules. Nothing is disclosed as to its use in a crystalline lens. Based on the complete lack of any teaching suggesting the desirability of using self-organizing fibrillar networks of DBS in a crystalline lens, one of ordinary skill in the art would not have been provided with any suggestion or motivation to inject DBS into an empty capsule of lens and thereby create a model of eye with cataract.

As noted almost insistently by the Federal Circuit, there **must** be some teaching, suggestion, or motivation to make the claimed limitations found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. The self-organizing networks of Wilder et al. and the denaturing and hardening of protein **inside** a crystalline lens with formalin and alcohol of Sugiura et al. and Grubbs et al. fail to rise to this level.

One of ordinary skill in the art clearly would not have gleaned from the teachings of the cited references the desirability of adding DBS to a crystalline lens. In other words, one of ordinary skill would not have had the motivation to pluck Wilder et al. from the prior art to ascertain the DBS component and thereby make the presently claimed invention without some motivation.

Accordingly, Applicants respectfully submit that the presently claimed invention is unobvious over the cited references and request reconsideration and withdrawal of the rejections to the presently pending claims.

## 3. **Rejection of Claims 11 and 18-19 under 35 USC § 103(a)**

The Office Action rejects claims 11 and 18-19 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,919,151 ("Grubbs et al.") in view of "Creating Cataract in a Pig Eye", J. Refractive Surg., May 1999 ("Sugiura et al."), and "Polymer Gelation Due to the Self Assembly of Dibenzylidene Sorbitol and Its Derivatives", Statistical Thermodynamics N.C. State Univ., (June 01,1999) ("Wilder"), and further in view of U.S. Patent No. 5,130,353 ("Fischer et al."). The Office Action states:

> Grubbs as viewed in combination with Sugiura and Wilder discloses all of the limitations of the claims with the exception of the specific materials claimed. Resin, glycerine and N-methyl-2-pyrrolidene are all known solvents, however, as disclosed in column 5, 53 to column 6, line 10 of Fisher. It would have been obvious to one of ordinary skill in the relevant art to modify the model disclosed by Grubbs as viewed with Sugiura and Wilder by injecting resin, glycerine and N-methyl-2-pyrrolidene into the device for the purpose of providing a composition which acts as a solvent.

Applicants respectfully traverse this rejection. However, claims 11 and 18-19 have now been canceled wherein the subject

matter of claims 18 and 19 have been incorporated into the independent claims 1 and 3. Therefore, the rejection is now moot since the arguments provided supra apply over the present rejection of the combination of Wilder et al., Sugiura et al. Grubbs et al. and Fisher et al.

However, with regard to the Fisher et al. Applicants note for the record that the reference compound is different from the presently claimed compound. In particular, Fisher et al. teaches a process for preparing photochromic material by dissolving a photochromic substance whose color changes by light into the mixture of poly(vinylpyrrolidone) and hydroxy propyl cellulose by the temperature of 180°C to 220°C, after cooled down applying it to the surface of the object.

However, the N-methyl-2-pyrrolidone used in the present invention is a solvent while the poly(vinylpyrrolidone) of Fisher et al. is a polymer of a synthetic resin wherein it is described in Example 1 as a polymer having a molecular weight of about 360,000. In other words, the N-methyl-2-pyrrolidone of the present invention is a polar solvent having a molecular weight of 109, and is the stable compound whose chemical formula is $CH_3$-N-$COCH_2CH_2CH_2$ whereas the poly(vinylpyrrolidone) of Fisher

et al. is a polymer of a synthetic resin. Therefore, Fisher et al. does not teach the presently claimed component of the now canceled claims.

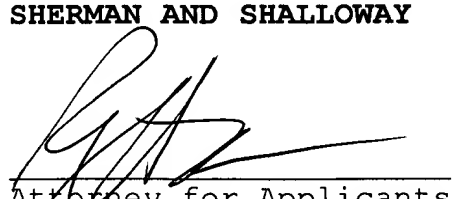
Accordingly, Applicants respectfully submit that the presently claimed invention is unobvious over the cited references and request reconsideration and withdrawal of the rejections to the presently pending claims.

**CONCLUSION**

In light of the foregoing, Applicants submit that the application is now in condition for allowance. The Examiner is therefore respectfully requested to reconsider and withdraw the rejection of the pending claims and allow the pending claims. Favorable action with an early allowance of the claims pending is earnestly solicited.

Respectfully submitted,

**SHERMAN AND SHALLOWAY**



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**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re the application of: )
UMEYAMA; NAKAKI )
Serial No. 09/834,886 )
Filed: April 16, 2001 )

Group Art Unit: 3712
Examiner: K. FERNSTROM

For: **A MODEL FOR TRAINING OF SURGICAL OPERATION OF CATARACT**

## Appendix A

Please amend the following claims according to the July 30, 2003, revision of 37 C.F.R. § 1.121 concerning a manner for making claim amendments.

1. (Currently amended) A model for cataract surgery, comprising:

a pig's eye which is prepared by injecting a self hardening chemical ~~chemicals selected from the group consisting of~~ , said self hardening chemical being dibenzylidenesorbitol, ~~polyhydric alcohol, methylbenzaldehyde, ethyl benzaldehyde and xylitol~~

a water soluble cellulose resin,

glycerin and

N-methyl-2-pyrrolidone into a crystalline lens capsule of said pig's eye wherein said crystalline lens capsule of said pig's eye is empty.

2. (Canceled)

3. (Currently amended) A model for cataract surgery in the corpus vitreum, wherein a false nucleus of a cataract is prepared by injecting a self hardening chemical ~~chemicals selected from the group consisting of~~ , said self hardening chemical being dibenzylidenesorbitol, ~~polyhydric alcohol, methylbenzaldehyde, ethyl benzaldehyde and xylitol~~

a water soluble cellulose resin,

glycerin and

N-methyl-2-pyrrolidone into an empty crystalline lens capsule of a pig's eye wherein said crystalline lens capsule of said pig's eye is empty.

4. (Canceled)

5. (Currently amended) The model for cataract surgery of claim 1, wherein ~~said~~ the self hardening ~~type chemicals are~~ chemical is injected from the posterior pole of said pig's eye.

6. (Canceled)

7. (Canceled)

8. (Canceled)

9. (Canceled)

10. (Currently amended) A method of using a pig's eye having an empty crystalline lens capsule, comprising the step of:

injecting a self hardening chemical ~~chemicals selected from the group consisting of~~ , said self hardening chemical being dibenzylidenesorbitol, ~~polyhydric alcohol, methylbenzaldehyde, ethyl benzaldehyde and xylitol~~

a water soluble cellulose resin,

glycerin and

N-methyl-2-pyrrolidone into an empty crystalline lens capsule of ~~the~~ pig's eye ~~wherein said~~.

11. (Canceled)

12. (Currently amended) The method of claim 10, wherein said crystalline lens capsule of pig's eye is emptied by phacoemulsification.

13. (Currently amended) The method of claim 10, wherein said crystalline lens capsule of pig's eye is emptied by aspiration.

14. (Currently amended) The model for cataract surgery of claim 1, wherein said crystalline lens capsule of ~~the~~ pig's eye is emptied by phacoemulsification.

15. (Currently amended) The model for cataract surgery of claim 1, wherein said crystalline lens capsule of ~~the~~ pig's eye is emptied by aspiration.

16. (Currently amended) The model for cataract surgery of claim 3, wherein said crystalline lens capsule of ~~the~~ pig's eye is emptied by phacoemulsification.

17. (Currently amended) The model for cataract surgery of claim 3, wherein said crystalline lens capsule of ~~the~~ pig's eye is emptied by aspiration.

18. (Canceled)

19. (Canceled)